K053408

DEC 2 2 2005

510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: December 6, 2005

Applicant: Nexa Orthopedics, Inc., (dba Futura Biomedical, LLC)
10675 Sorrento Valley Road, Suite 100
San Diego, CA 92121

Telephone: 858-866-0660
Fax: 858-866-0661
Contact: Louise M. Focht

Device Name:	Nexa bone plate and screw system
Device Trade Name:	Nexa bone plate and screw system
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3030
Product Code:	87 HRS
Predicate Device:	K051884 Wright Medical Charlotte Small MTP Fusion Plate K033639 Acumed Lower Extremity Congruent Plate System
Registration Number:	2030833
Owner Operator Number:	9028319

Device Description:

The Nexa Orthopedics bone plate and screw system is a system of plates and screws made of Stainless Steel (316L) and Titanium (6AL-4V ELI) intended to be implanted into the bones of the foot, ankle, hand, wrist, ulna and radius. The plates are provided in 4 sizes, right and left configuration. The screws are provided in 2 diameters 2.7 and 3.2 and lengths from 12-28 mm. The plates and screws are used for fracture fixation, fusion, and osteotomy of the bones of the foot.

Indications for Use:

The bone plate and screw system is intended for use in providing fixation during fractures, fusions and osteotomies. The system consists of plates and screws for treatment of the phalanges, and metatarsals.

Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Wright Medical Charlotte Small MTP Fusion Plate

Regulatory Class: II
Product Code: 87 HRS

Table 1 summarizes similarities and differences between the Nexa Orthopedics and the Wright Medical Charlotte Small MTP fusion plate system.

Item	*Nexa Orthopedics System*	*Wright Medical Plate System*
Product Name	Nexa bone plate and screw system	Wright Medical Charlotte Small MTP Fusion Plate
Use	Single use	Single use
Fixation	Screw	Screw
Material	Stainless Steel	Stainless Steel
Sizes	Plates 4 sizes, right and left Screws dia 2.7mm, 3.2mm , length 12-28mm	Plates 2 sizes, right and left Screws dia 2.7mm, 3.2mm , length 8-24mm
Indications for use	The bone plate and screw system is intended for use in providing fixation during fractures, fusions and osteotomies. The system consists of plates and screws for treatment of the phalanges, and metatarsals.	The Charlotte Small MTP Fusion Plate is intended to help increase the rate of bony union, and to maintain the position of the toe during fusion. Once the joint has fused, the plate is secondary in the transmission of gait forces. • Fractures, osteotomies or arthrodesis of the first metarsal-phalangeal joint • Deformity due to hallus valgus • Deformity due to arthritis in the first metatarsal-phalangeal joint • Loss of motion-hallux rigidus • Pain associated with osteoarthritis or rheumatoid arthritis in the first metatarsal-phalangeal joint • Revision procedures where other treatments or devices have failed; and • Chronic instability in the first metatarsal-phalangeal joint

Similarities of the Nexa Orthopedics bone plate and screw system and Charlotte small MTP Fusion Plate system include:

Both devices are: intended for single use only; intended for surgical implantation longer than 30 days; both devices are a system of plates and screws used for fixation of fracture, fusion, osteotomies, of the metatarsal and phalangeal bones; both devices are made of

industry standard materials, no new materials are introduced in either product; Both devices are comparably sized; both devices have the same indications for use.

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Ms. Louise Focht
Vice President of Research and Development
Nexa Orthopedics, Inc.
10675 Sorrento Valley Road, Suite 100
San Diego, California 92121

Re: K053408
Trade/Device Name: Nexa Bone Plate and Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 6, 2005
Received: December 7, 2005

Dear Ms. Focht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (If Known): K053408
Device Name: Nexa bone plate and screw system

Indications for Use:

The bone plate and screw system is intended for use in providing fixation during fractures, fusions and osteotomies. The system consists of plates and screws for treatment of the phalanges, and metatarsals bones.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053408